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FDA Files

A more transparent FDA

By Steven Niles

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FDA is under new management. Margaret Hamburg, M.D., was sworn in to her position as FDA commissioner May 22, 2009, by Health and Human Services Secretary Kathleen Sebelius. Dr. Hamburg is an authority on global health, public health systems, infectious disease, bioterrorism, and emergency preparedness. She served as the Nuclear Threat Initiative's founding VP for the Biological Program. Before joining NTI, she was the assistant secretary for planning and evaluation, U.S. Department of Health and Human Services. Prior to this, she served for six years as the commissioner of health for the City of New York and as the assistant director of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health.

Industry observers have high expectations for the new commissioner. "I hope the new commissioner will implement the Obama administration's focus on fact-based analysis and increase, even further, the emphasis on a risk-based approach," says Wade Speir, principal consultant, life sciences and healthcare practice, PA Consulting Group (paconsulting.com). "All too much effort and energy are still wasted by industry fixing minor items they believe will be caught rather than what they believe are more important issues that they do not think will be discovered or cited by inspectors."

In addition, Mr. Speir believes that an increased emphasis on flexibility is needed, allowing for more dynamic changes to clinical trials to increase development efficiency. "Even greater flexibility will be required as we enter the age of personalized medicine with advanced use of diagnostics and custom compounding for groups as well as, eventually, individuals," Mr. Speir told *Med Ad News*.

Dan Walsh, a member of PA Consulting's management team in the life sciences and healthcare practice, hopes that Dr. Hamburg will focus on accelerating the review and clearance of important medical technologies for use. At the same time, Mr. Walsh would like to see increasing robustness and sophistication of reviews so that the most effective therapeutic approaches can be brought to patients quickly.

Based on Dr. Hamburg's bioterrorism and public health background, FDA may be taking a new direction, according to Nancy Beesley, executive VP, HC&B Healthcare Communications (hcbhealth.com), a full-service international marketing communications agency. "Hamburg seems to have no obvious ties – either negative or positive – to pharmaceuticals companies, which is probably why she was approved so quickly by the Senate," Ms. Beesley says. "She seems to be a public health specialist based on her prior posts, so we can expect to see the direction of the FDA changing from a heavy

emphasis on drug approval issues to more of a holistic food and drug safety agency. Will that mean speedier approvals? Probably not. But it might mean less bureaucracy down the road, and less protracted infighting between pharma and the government.”

One of the first tasks of the new commissioner was the formation of a task force to develop recommendations for enhancing the transparency of the agency’s operations and decision-making process. To support the efforts of the transparency task force, FDA has issued a Federal Register notice announcing a public meeting in June to solicit recommendations on how the agency can make useful and understandable information on its activities and decisions more available.

The transparency task force will seek public input on issues related to transparency; recommend ways that the agency can better explain its operations compatible with the appropriate protection of confidential information; identify information FDA should provide about specific agency operations and activities, including enforcement actions and product approvals; identify problems and barriers, both internal and external, to providing useful and understandable information about FDA activities and decision-making to the public; identify appropriate tools and new technologies for informing the public; recommend changes to FDA’s current operations, including internal policies and guidance, to improve the agency’s ability to provide information to the public in a timely and effective manner; recommend legislative or regulatory changes, if appropriate, to improve FDA’s ability to provide information to the public; and submit a written report to the commissioner on the transparency task force’s findings and recommendations.

FDA has set up a blog at fdatransparencyblog.fda.gov where the public can offer suggestions about how to improve transparency at the agency. In addition to the blog, comments can be submitted electronically to the federal register at regulations.gov.

Mr. Speir and Mr. Walsh at PA Consulting believe that FDA needs to follow the Obama administration’s lead in making all of its expenditures and non-proprietary findings as public as possible. Furthermore, they believe that the agency should join with government departments – such as Health and Human Services – pharmaceutical manufacturers, payers, and providers to drive the collection of health information, including national biobank, drug efficacy database, et cetera.

They also call for a sensible collection and distribution of statistics and epidemiological and prevalence data that would emerge from electronic patient records. Mr. Speir and Mr. Walsh acknowledge that this would require strong, multi-level protections of individual and group privacy.

Ms. Beesley would like to see a lot more transparency in the approval process of pharmaceuticals and medical devices. She believes that all manufacturers, from the very large to the very small, should be able to view the process by which drugs are approved and what parameters are being used to judge them. Having recently worked with a smaller drug company trying to bring a new drug to market, Ms. Beesley saw the company completely shut out of the deliberative process at FDA.

Ms. Beesley would also like to see FDA do a better job of informing the American public regarding the food supply or recalls. “They need to utilize the Web more to communicate clearly and quickly with Americans,” she says.

FDA must tread carefully when it comes to transparency, according to Ilyssa Levins, president, Center for Communication Compliance (communicationcompliance.com). The premature release of information can harm patients should small drug risks cause public fear, negatively affecting adherence and persistence to drug therapy. How the need for transparency will be reconciled with the need to protect legitimate trade secrets also remains to be seen.

“FDA’s regulation and enforcement will continue to intensify under Hamburg’s watch,” Ms. Levins told *Med Ad News*. “Like FDA, industry must be more transparent about the risks and benefits of its own drugs. In addition to warnings letters (and DOJ indictments), false promotional claims cause public fear and further damage the industry’s reputation. Balance must be carefully maintained in drug promotion. In addition to internal compliance savvy, industry must reduce literacy gaps among its promotional agencies.”

Ms. Levins hopes Dr. Hamburg will positively affect the agency’s direction, and that of the industry.

“Both parties have an opportunity to perfect their balancing act as they optimize patient outcomes and public trust through responsibly executed transparency strategies,” Ms. Levins says.

Improved communication and visibility are critical to making the system more efficient for manufacturers and more effective for patients and their families, according to Jeff Kozloff, CEO, Verilogue (verilogue.com). He believes that a truly progressive advance would include all critical stakeholders involved in the continuum of care, specifically the communication between physician and patients at the point of care, as key members of a more transparent and real-time feedback loop.

“My industry colleagues are encouraged by the initial steps taken by the new FDA leadership and welcome additional opportunities to collaborate and communicate throughout the decision-making and monitoring process,” Mr. Kozloff says. “Improving transparency and lines of communication, however, should not stop with just the relationship between the agency and pharma manufacturers/marketers.”